Otto Bock®

QUALITY FOR LIFE

K052771

MAY 3 2006

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	OTTO BOCK HealthCare LP
2.	*Address:*	Two Carlson Parkway N., Suite 100 Minneapolis, MN 55447-4467
3.	*Telephone:*	763-489-5142
4.	*Contact Person:*	Bill Clover
5.	*Date Prepared:*	February 8, 2006
6.	*Registration Number:*	2182293

B. Device

1.	*Name:*	Sensor Walk™
2.	*Trade Name:*	Sensor Walk™
3.	*Common Name:*	Electronic Stance Control KAFO
4.	*Classification Name:*	Orthosis, Limb Brace
5.	*Product Code:*	IQI
6.	*Class:*	I
7.	*Regulation Number:*	890.3475

Customer Service, Technical Support, and General: 800.328.4058 • Fax 800.962.2549
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Customer Satisfaction Hotline: 877.627.6583
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C. Identification of Legally Marketed Devices

1. *Name:* OTTO BOCK FreeWalk
2. *K Number:* Not Applicable
3. *Date Cleared:* Not Applicable

D. Description of the Device

The Sensor Walk is a microprocessor-controlled Knee Ankle Foot Orthosis (KAFO) designed to help wearers achieve a safer, more physiologically correct gait. It does this by unlocking the knee joint when the wearer is ready for swing phase and locking it again for stability during stance phase.

The Sensor Walk system includes an onboard microprocessor, a clutch spring knee joint, foot pressure sensors, a knee angle sensor, a battery, and a battery charger. When the sound limb has been loaded during walking and the affected side is about to enter swing phase (with the toe still on the ground) the microprocessor reads signal information from the foot and knee sensors and allows the knee to go into flexion. When the orthosis begins to extend again, the knee will enter a stable phase, preventing any flexion while allowing full extension for stance phase. The Sensor Walk will support the wearer if they load it at any point while it is extending, offering them exceptional stability. Wearers can disengage the knee joint, such as for sitting, simply by pressing the manual release switch.

The Sensor Walk offers 12 hours of continuous use before it needs to be recharged, and contains an audible warning to alert the use if the battery is running low.

When the Sensor Walk is turned off, it offers the stability of a traditional locked KAFO throughout the gait cycle.

The Sensor Walk has Manual Release Function. A control collar at the knee joint can be manually pushed back to temporarily override the locking mechanism and put the joint into free swing mode. As soon as the collar is released, the joint will be able to lock.

To override the Sensor Walk's locking mechanism for a longer period, a Manual Release Rocker Switch can be pressed to lock the control collar in the free swing

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mode. When the Manual Release Rocker Switch is pressed and the joint is in free-swing mode, the switch will show an amber dot to indicate that caution should be used. In normal operating mode, the switch will show a green dot indicating that the locking feature will function normally.

The Sensor Walk™ is comprised of the following parts: a traditional, double-upright KAFO with a free-articulating medial knee joint; a lateral mechanical clutch, 6 spring knee joint, microprocessor-controlled electronics, foot sensors, a battery, and a battery charger.

The foot sensor plate includes 4 sensors arranged in a straight line on the bottom of the foot plate. They are numbered from 1 to 4, beginning with the most posterior. The sensors overlap by 3/8 inch (10mm), and are wired to a sensor selection switch located in the electronics of the Sensor Walk. The Sensor Walk comes delivered with sensors 1 and 2 activated, but, if necessary, other sensors can be selected to optimize patient fitting.

The Sensor Walk is delivered with the following components:

- Fabricated KAFO with Sensor Walk (17B500) knee joint and foot sensor (520E500)
- Battery (517B20) and Charger (517L20)
- Sensor Walk Instructions for Use

The Sensor Walk comes in either a right or left, laminated or thermoplastic. The Order Numbers are as follows:

- 17B500 = R-L300 – Laminated Right
- 17B500 = L-L300 – Laminated Left
- 17B500 = R-T300 – Thermoplastic Right
- 17B500 = L-T300 – Thermoplastic Left

E. Intended Use Statement

The Sensor Walk is intended solely for the orthotic fitting of the lower limbs and is intended for use by patients who are community ambulators The Sensor Walk is intended for forward walking on level surfaces. when the power is turned on, only, it is not intended for sports or aggressive use.

The Sensor Walk is indicated for patients who exhibit knee instability in the sagittal plane while bearing weight during the stance phase of their gait cycle.

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Patients *must*:

- Have hip extensor strength of at least grade 3 (against gravity),
- Have the muscle strength in their torso or pelvis required to swing the Sensor Walk forward while walking,
- Have a gait in which the step length on level ground exceeds the length of the opposing foot,
- Weigh 300 pounds or less,
- Be able to understand and carry out the instructions.

F. Technological Characteristics Summary

The Sensor Walk is substantially equivalent to the OTTO BOCK FreeWalk which is a Class I. Exempt device according to 21CFR Part 890.3475.

Similarities between both KAFOs are the following:

- KAFO
- Steel Uprights
- Fabricated
- Indications
- Materials
- Weight Limit

Differences are the Sensor Walk allows the knee joint to unlock in late stance phase, but not before weight is transferred to the leading limb. The FreeWalk has automatic lock initiated by knee extension.

The Sensor Walk is microprocessor controlled by sensors in the footplate. The FreeWalk is not controlled by sensors but by a mechanical locking mechanism. The Sensor Walk is battery operated that powers the knee joint for 12 hours.

None of the differences raise any new questions of safety or effectiveness that have not been addressed by the developers (OTTO BOCK and Mayo Clinic).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2006

Otto Bock HealthCare LP
% Mr. Bill Clover
Vice President Research and Development
Two Carlson Parkway N., Suite 100
Minneapolis, Minnesota 55447-4467

Re: K052771
Trade/Device Name: Sensor Walk
Regulation Number: 21 CFR 890.3475
Regulation Name: Limb orthosis
Regulatory Class: Class I
Product Code: IQI
Dated: February 8, 2006
Received: February 28, 2006

Dear Mr. Clover:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K052771

Device Name: Sensor Walk

Indications for Use:

The SensorWalk is intended to lock the knee joint during the stance phase and to unlock the knee joint during the swing phase when walking forward on level surfaces. It is intended solely for the orthotic fitting of the lower limbs of patients who are community ambulators and who:

- Exhibit knee instability in the sagittal plane while bearing weight during the stance phase of their gait cycle;
- Have hip extensor strength of at least grade 3 (against gravity);
- Have the muscle strength in their torso or pelvis required to swing the SensorWalk forward while they are walking;
- Have a gait in which the step length on level ground exceeds the length of the opposing foot;
- Weigh 300 pounds or less; and
- Are able to understand and carry out the instructions.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

510(k) Number K052771

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)